

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 75213

CHEMISTRY REVIEW(S)

1. CHEMISTRY REVIEW NO. 3

2. ANDA # 75-213

3. NAME AND ADDRESS OF APPLICANT

Spear Pharmaceuticals
13100 Ponderosa way
Fort Myers, FL 33907

4. LEGAL BASIS FOR SUBMISSION

The firm certify that to in their opinion and to the best of their knowledge the patents have expired.

5. SUPPLEMENT(s)

6. PROPRIETARY NAME

7. NONPROPRIETARY NAME

8. SUPPLEMENT(s) PROVIDE(s) FOR:

Tretinoin

N/A

9. AMENDMENTS AND OTHER DATES:

Original 9/30/97
Amendment 11/24/97
Amendment 9/14/98
Amendment 8/5/98
Amendment 9/28/98
Amendment 10/14/98
Amendment 11/13/98

10. PHARMACOLOGICAL CATEGORY

11. Rx or OTC

Treatment of acne vulgaris

Rx

12. RELATED IND/NDA/DMF(s)

DMF's

13. DOSAGE FORM

14. POTENCY

Cream

0.1% w/w

15. CHEMICAL NAME AND STRUCTURE

Retinoic acid

16. RECORDS AND REPORTS

17. COMMENTS

18. CONCLUSIONS AND RECOMMENDATIONS

The application is approvable -

19. REVIEWER: DATE COMPLETED:

Nashed E. Nashed, Ph.D.

12/3/98

Supervisor: Paul Schwartz, Ph.D.

12/4/98

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Page(s) //

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Chemistry